

Translation

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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

|   |   |  |
|---|---|--|
| Applicant's or agent's file reference<br>03038WO0   | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |  |
| International application No.<br>PCT/JP2003/012732  | International filing date (day/month/year)<br>03 October 2003 (03.10.2003)  | Priority date (day/month/year)<br>04 October 2002 (04.10.2002) |
| International Patent Classification (IPC) or national classification and IPC<br>C07K 14/705, 16/28, A61K 9/127, 39/395, 51/00, A61P 35/00, C12N 15/09 |   |  |
| Applicant<br>MITSUBISHI PHARMA CORPORATION  |   |  |

|   |
|---|
| 1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.   |
| 2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.<br><br><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).<br><br>These annexes consist of a total of _____ sheets.   |
| 3. This report contains indications relating to the following items:<br><br>I <input checked="" type="checkbox"/> Basis of the report<br>II <input type="checkbox"/> Priority<br>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability<br>IV <input type="checkbox"/> Lack of unity of invention<br>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement<br>VI <input type="checkbox"/> Certain documents cited<br>VII <input type="checkbox"/> Certain defects in the international application<br>VIII <input type="checkbox"/> Certain observations on the international application |

|  |  |
|--|--|
| Date of submission of the demand<br>03 October 2003 (03.10.2003) | Date of completion of this report<br>20 February 2004 (20.02.2004) |
| Name and mailing address of the IPEA/JP                          | Authorized officer   |
| Facsimile No.  | Telephone No.  |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2003/012732

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

- These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP03/12732

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 31, 32

because:

☒ the said international application, or the said claims Nos. 31, 32  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions of claims 31 and 32 concern a method for diagnosing and treating the human body by therapy, which does not require an examination by the International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and Rule 67.1(iv).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 31, 32

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP03/12732

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

|                               |        |                   |     |
|-------------------------------|--------|-------------------|-----|
| Novelty (N)                   | Claims | 5-11              | YES |
|                               | Claims | 1-4, 12-30, 33-35 | NO  |
| Inventive step (IS)           | Claims | 5-11              | YES |
|                               | Claims | 1-4, 12-30, 33-35 | NO  |
| Industrial applicability (IA) | Claims | 1-30, 33-35       | YES |
|                               | Claims |                   | NO  |

### 2. Citations and explanations

Document 1: EP 520499 A1 (Mitsubishi Kasei Corp.)  
 Document 2: EP 399257 A1 (Oregon Health Sci. U.)  
 Document 3: Cancer Research 61, 4048-4054 (2001)  
 Document 4: WO 92/08131 A1 (Univ. Columbia New York)  
 Document 5: WO 02/057741 A2 (Molecular Discoveries, L. L. C.)  
 Document 6: Cancer Research 47, 3873-3879 (1987)  
 Document 7: Surg. Today 25, 244-250 (1995)  
 Document 8: Cancer Research 53, 3233-3236 (1993)  
 Document 9: Virchows Archiv A: Pathological Anatomy and Histopathology 405 (1) 69-83 (1984)

Document 1 does not discuss the identification of antigens, but it does describe the antibody of the present application and use thereof.

Document 2 describes an antigen on the surface of tumor cells, and the transplantation of those cells to the brain.

Documents 3-7 describe antigens on the surface of tumor cells and antibodies thereof.

Document 8 describes an antigen on the surface of tumor cells.

Document 9 states that the shape of myosin is altered in early stage metastatic breast cancer.

#### Claims 1-4

Documents 2-8 cited in the international search report describe the inventions concerning the antigen of claims 1-4, and therefore those inventions lack novelty and an inventive step.

#### Claims 5-11

None of the documents cited in the international search report discloses the inventions of claims 5-11 concerning the use of the cytoskeleton and myosin as antigens, and therefore those inventions are novel and involve an inventive step.

(Continued)

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

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**PCT/JP03/12732**

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V:

**Claims 12-30**

Based on the description in document 1 cited in the international search report, the inventions of claims 12-30 concerning ligands and antibodies lack novelty and an inventive step.

**Claims 33-35**

Based on the descriptions in documents 1-7 cited in the international search report, the inventions of claims 33-35 concerning ligands lack novelty and an inventive step.